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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/912,968	07/25/2001	Stanton B. Dotson	38-21(51862)B	6793

7590 03/08/2007

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EXAMINER	
BAUSCH, SARAE L	
ART UNIT	**PAPER NUMBER**
1634	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/912,968	DOTSON ET AL.	
	Examiner	Art Unit	
	Sarae Bausch	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/01/2006 has been entered.

2. Currently, claims 53-69 are pending in the instant application. Claims 1-52 have been cancelled and claims 53-69 have been newly added. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. New grounds of rejection are set forth below. **This action is Non-Final.**

Priority

3. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the

application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath

or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Specification

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. The specification on page 40, last paragraph contains the hyperlink http://www.pebio.com. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 53-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a). Claims 53, 68 and 69 recites the limitation "producing a complementary DNA from said mRNA" in line 4 of claim 53, 68 and 69. There is insufficient antecedent basis for this limitation in the claim. The preamble recites "the second transgenic nucleic acid molecule is

capable of producing an mRNA" however no other preceding steps of "producing a complementary DNA from said mRNA" require obtaining an mRNA molecule. It is unclear if the complementary DNA that is produced is from the mRNA from the second transgenic nucleic acid molecule, if the mRNA is from the first transgenic nucleic acid molecule, or a different mRNA molecule and it is unclear the relationship of the first and second transgenic nucleic acid to the mRNA from which the cDNA is produced. The claim does not require any active process steps of producing or obtaining an mRNA molecule and therefore it is unclear the complementary DNA that is produced by said mRNA.

(b). Claim 64 recites the limitation "the label" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 64 depends from claim 62 and 53 and neither claim 62 or claim 53 recite "a label".

(c). Claim 66 recites the limitation "said primer pair" in line 1 and "the probe" in line 4 of claim 66. However, claim 66 depends from claim 64, 62 and 53 and claims 53, 62, and 64 do not recite a primer pair. There is insufficient antecedent basis for this limitation in the claim.

(d). Claim 67 is indefinite over the recitation of "further comprising Southern Blotting, Northern Blotting or RNAse protection assay". Claim 67 depends from claim 53 and claim 53 requires the process steps of producing a complementary DNA, amplifying a complementary DNA and detecting the complementary DNA by hybridization with at least one oligonucleotide designed to hybridized with the complementary DNA. However the method steps of northern blotting and RNAse protection assay require detection of a transcript (RNA). Northern blotting requires the use of a DNA probe to hybridize to an RNA transcript and RNAse protection assay requires an RNA sample digested with an RNAse. The claim is ambiguous because it is not

clear how a RNAase protection assay or a Northern blotting assay relates to the method of detecting the expression of a first transgenic nucleic acid molecule as the process steps of claim 53 do not require the direct analysis or direct detection of a RNA sample. It is unclear how performing the steps of a Northern Blot assay or RNAase protection assay will result in the method of detecting the expression of a first transgenic nucleic acid molecule because the claim does not clearly set forth how the steps of Northern Blotting or RNAase protection assay is used to further comprise the method of detecting the expression of a first transgenic nucleic acid molecule and therefore the metes and bounds of the claim are vague and indefinite.

(e). Claims 54-67 depend from claim 53 and are therefore vague and indefinite for the reasons applied to claim 53.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 53-55, 59-60, 63, 65 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Fleming et al. (The Plant Journal (1996) 10(4), pp. 745-754).

With regard to claim 53, 59, and 63, Fleming et al. teach a method of RT-PCR analysis of gene expression of rbcS genes in transgenic plants (see page 745, 2nd column, 1st paragraph). Fleming et al. teach a first transgenic nucleic acid molecule, coding region of each rbcS gene operably linked to a second transgenic nucleic acid molecule, 3'UTR region of each gene (see

figure 6). Fleming et al. teach RT-PCR of each rbcs gene by producing a complementary DNA from mRNA (see page 752, 2nd column, 1st full paragraph) and amplifying the complementary DNA (see page 752, 2nd column, last para. cont'd to page 753). Fleming et al. teach following amplification, the PCR reaction products were blotted on a nylon membrane, hybridized with a labeled DNA body probe for rbcS (claim 63), wherein the probe bound all amplified rbcS sequences (at least one oligonucleotide designed to hybridize with complementary DNA). Fleming et al. teach estimating signal intensity for each sample (wherein the hybridization indicates expression of the first transgenic nucleic acid molecule) (see page 753, 1st column, 1st full paragraph). It is noted, the claims require amplification of the cDNA and hybridization of said cDNA with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid whereby hybridization indicates expression of the 1st transgenic nucleic acid sample and Fleming teaches amplification of the cDNA (rbcS 3' UTR regions of each gene) and hybridization of the cDNA with at least one oligonucleotide designed to hybridize to the second transgenic nucleic acid (DNA body probe) to indicate expression of the 1st transgenic nucleic acid sequence (each rbcS genes) (see page 753, 1st full column, 1st paragraph).

With regard to claim 54 and 60, Fleming et al. teach RT-PCR of rbcS gene-specific amplification by using a 5' primer in the coding region, AF10, and a 3' gene specific primer for each 3'UTR of genes rbcs1, rbcs2, rbcs3a-c, AF21-25 (see figure 6). Fleming et al. teach following amplification, the PCR reaction products were blotted on a nylon membrane, hybridized with a labeled DNA body probe for rbcS, wherein the probe bound all amplified rbcS sequences (at least one oligonucleotide designed to hybridize with complementary DNA). Fleming et al. teach estimating signal intensity for each sample (quantitating mRNA transcribed

from the second transgenic nucleic acid , quantitative RT-PCR) (see page 753, 1st column, 1st full paragraph).

With regard to claim 55, Fleming et al. teach a second transgenic nucleic acid molecule capable of producing mRNA that is a 3'UTR sequence of the rbcS gene (See figure 6).

With regard to claim 65, Fleming et al. teach RT-PCR of rbcS gene-specific amplification by using a 5' primer in the coding region, AF10, and a 3' gene specific primer for each 3'UTR of genes rbcs1, rbcs2, rbcs3a-c, AF21-25 (see figure 6) (a pair of oligonucleotide primers and an oligonucleotide probe designed to hybridize to the second transgenic nucleic acid molecule in a 5' nuclease assay). It is noted that the claim does not require performing a 5' nuclease assay and requires only that the probe is designed to hybridize to the second transgenic nucleic acid molecule and therefore the probe taught by Fleming et al. is a probe that is designed to hybridize to the second transgenic nucleic acid molecule in a 5' nuclease assay.

With regard to claim 67, Fleming et al. teach following amplification, the PCR reaction products were blotted on a nylon membrane and hybridized with a labeled DNA body probe for rbcS (southern blotting) (see page 753, 1st column, 1st full paragraph).

Response to Arguments

9. The response traverses the rejection on pages 6-7 of the response mailed 11/06/2006. The response asserts that Fleming does not teach nucleic acid molecule operably linked to a second transgenic nucleic acid molecule by detecting complementary DNA by hybridizing with at least one oligonucleotide designed to hybridize with the complementary DNA wherein hybridization indicated expression of the first transgenic nucleic acid. This response has been

thoroughly reviewed but not found persuasive. Fleming et al. does teach a first transgenic nucleic acid, rbcS coding region operably linked to a second transgenic nucleic acid, the 3' UTR region of the rbcS gene and further teach analysis by RT-PCR of the rbcS transcripts (see figure 6).

The response asserts on page 7, 1st full paragraph, Fleming has no need to determine expression of a first transgenic nucleic acid molecule by hybridization of complementary DNA with at least one oligonucleotide because they detect expression of a first transgenic nucleic acid molecule by fluorescence imagining. This response has been thoroughly reviewed but not found persuasive. Fleming et al. teach a combined approach of fluorescent imaging of GUS reporter gene expression *and* RT-PCR analysis (see page 745, 2nd column, last full paragraph). Furthermore, a reference may be directed to an entirely different problem than the one addressed by the inventor, yet the reference is still anticipatory if it explicitly or inherently discloses every limitation recited in the claims. In the instant case, Fleming et al. teach detection of a first transgenic nucleic acid, rbcS coding region operably linked to a second transgenic nucleic acid, 3'UTR region by RT-PCR (see figure 6) which anticipates the claimed invention.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 53-56, 58-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al. (DNA, 1988) in view of Freeman et al. (*Biotechniques,* 1999).

Hunt et al demonstrates the transformation of a tobacco plant with a plasmid carrying the 3' non coding strand of the pea rbcS-E9 3'region (2^{nd} transgenic nucleic acid) (claim 55-56) and CAT gene (1^{st} transgenic nucleic acid) (figure 1A and page 330, 2^{nd} column, last paragraph). Hunt et al. disclose the 3' non coding strand of pea rbcS E-9 which comprises a region that has greater than 15 and greater than 100 contiguous base pairs that are identical to SEQ ID NO: 2 (claims 61-62) (figure 2a, positions 1- 633 aligns with positions 5-637 of SEQ ID No. 2, see alignment) Hunt detects the rbcS-E9 3' region by the S1 nuclease assay (p. 331, 1^{st} –2^{nd} column, *RNA isolations and S1 nuclease protection analysis*) The sequence disclosed in figure 2 by Hunt comprises SEQ ID No. 7-9 (see alignments) (claim 58 and 68). Hunt et al. teach S1 nuclease assay was performed by labeling DNA using Klenow in the presence of (α-^{32}P) dATP of the rbcS region and therefore detection of CAT gene (see page 331, 1^{st} column, 2^{nd} full paragraph). Hunt et al. teach probes were hybridized (oligonucleotide designed to hybridization to cDNA) to the rbcS region for protection during the S1 nuclease thereby detecting the 2^{nd} transgenic nucleic acid and the 1^{st} transgenic nucleic acid (see figure 3-4). Hunt et al. does not teach the amplification by PCR or RT-PCR, quantitative and competitive RT-PCR, or the primers utilized for the amplification.

Freeman teaches the benefits of PCR, specifically utilizing quantitative RT-PCR, both competitive and non-competitive (pp. 116-117) to quantify mRNA (claim 54, 59-60) (see page 116-117). Freeman teaches the use of primers and a probe for PCR assays and specifically teaches the primers can be either gene specific or non-specific (see pg. 113, 3^{rd} column, 1^{st}

paragraph). Freeman teaches detection of amplified products can be performed by hybridization using southern blot or fluorescence detection (see pg. 114, 2nd column, 1st paragraph). Freeman et al. teach that real time product monitoring to improve quantitation which includes 5' exonuclease activity of Taq DNA polymerase through the use of sequence specific fluorogenic hydrolysis or hybridization (claim 65, 67) (see pg. 114, 2nd column, 1st and 2nd paragraph). Freeman teach probe used for hybridization detection of amplified products have a detectable fluorophoric label (claim 63-64) (see pg. 114, 2nd column, 2nd paragraph). Freeman et al. teach that RT-PCR represents a sensitive and powerful tool for analyzing RNA (see abstract). Freeman teaches that no other technique offers the potential to rapidly and quantitatively analyze a number of gene products from multiple small samples in a multiplex format (see pg. 122, 3rd column, last paragraph).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention was made to improve the S1 nuclease detection assay method of Hunt et al to include quantitative by RT-PCR, including amplification, primers and probes designed for RT-PCR, as taught by Freeman because Freeman teaches that quantitative RT-PCR provides increased sensitivity for RNA detection. An ordinary artisan would have been motivated to use quantitative RT-PCR amplification process, including a primers and probes with a fluorescent label along with a 5' nuclease assay instead of the S1 nuclease assay in the detection method of Hunt et al, for increased speed, specificity and decreased background as taught by Freeman et al. Furthermore, Freeman et al. teaches the advantages of improved RNA analysis and detection by RT-PCR.

With regard to the oligonucleotides (primers/ probes) of claims 58, 66, and 68, it would have been further *prima facia* obvious to one of ordinary skill in the art to design primers and probes for use in the method of Hunt in view of Freeman. The ordinary artisan would be motivated to generate probes and primers for the improved method of RNA detection of Hunt in view of Freeman, and in doing so, would generate a number of probes and primers including those with SEQ ID NO: 7, 8, 9 and 28 for use in the RNA detection method of Hunt and Freeman. These sequences are considered functionally equivalent in carrying out the amplification and detection step in the RT-PCR method for detection the 3' noncoding strand of the pea rbcS-E9 3'region of Hunt in view of Freeman, absent secondary considerations.

Response to Arguments

12. The response traverses the rejection on page 8 of the response mailed 12/01/2006. The response asserts that the examiner asserts that Hunt detects the rbcS by S1 nuclease assay and therefore detects the second transgenic nucleic acid and asserts that the claims are directed to detection of the first transgenic nucleic acid. This response has been thoroughly reviewed but not found persuasive. The claims are drawn to a method of detecting a first transgenic nucleic acid, by detection of a second transgenic and detection of second transgenic indicates expression of the first transgenic. Hunt et al. teach detection of a second transgenic nucleic acid, rbcS E9 gene by s1 nuclease assay and hybridization. Hunt et al. teach the CAT gene is operably linked to the rbcS E9 gene (see figure 1), therefore detection of the entire rbcS E9 3'UTR by S1 nuclease assay and hybridization will necessarily also detection expression of the CAT gene (first transgenic nucleic acid). Alternatively, the first transgenic nucleic acid could be interpreted

to be the entire pAH10 and the second transgenic nucleic acid is the rbcS E9 3'UTR and therefore detection of the rbcS E9 3'UTR will necessarily result in the detection of the entire pAH10 nucleic acid. Therefore, the method of detecting the rbcS 3'UTR gene by quantitative RT-PCR, as taught by Hunt in view of Freeman will result in a method of detecting expression of a first transgenic nucleic acid, CAT gene, operably linked to a second transgenic nucleic acid gene, rbcS E9 3'UTR by producing a cDNA from RNA of the rbcS E9 3'UTR, amplifying the cDNA by primers, including those of SEQ ID No. 7-9 and detecting hybridization with an oligonucleotide that is designed to hybridized to a second transgenic nucleic acid molecule, rbcS E9 3'UTR, using a probe including a probe with a sequence of SEQ ID No. 28 to detect expression of a first transgenic nucleic acid, CAT gene.

Conclusion

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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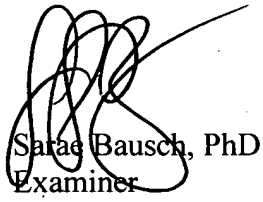

Sarae Bausch, PhD.
Examiner
Art Unit 1634